

REMARKS

Status of the Claims

Upon entry of the foregoing amendments, claims 1-38 are pending. Claims 11 and 31 have been amended and new claims 33-38 have been added. Support for these amendments is found throughout the specification and in the claims as originally filed. *See e.g.*, pages 3-4, 8, 11-12, 19-22 and originally filed claims 11, 13, 15, 19 and 31. Applicants respectfully submit the above amendments do not constitute new matter.

Objections to the Specification

The Office Action notes that the trademark PDS/1000-He Bio Rad Biolistic is used in the specification. Applicants have amended the specification to capitalize this trademark.

Statement of Substance of Interview Under 37 C.F.R. § 1.133(b)

In accordance with 37 C.F.R. § 1.133(b) and M.P.E.P. § 713.04, Applicants provide a summary of the interview held on March 26, 2008 with Supervisory Examiner Anne Marie Grunberg and Examiner Brendan Baggot. Applicants thank Examiners Grunberg and Baggot for agreeing to conduct the interview and appreciate the courtesies extended by the Examiners.

During the interview, Applicants addressed the outstanding rejections under 35 U.S.C. § 112. Applicants argued that the disclosure of SEQ ID NO: 1 and the nucleotide sequences that encode SEQ ID NO: 1 is adequate to comply with the written description requirement. Applicants also explained the specification provides the requisite guidance for one of skill in the art to make and use these nucleotide sequences. In particular, Applicants directed the Examiners' attention to Tables 1 and 2, which show the various sequences falling within the provisos set forth in the claims. The Examiners indicated that the rejections under 35 U.S.C. § 112 would likely be withdrawn after consideration of Applicants' written response.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

Claims 24-30 stand rejected under 35 U.S.C. § 112, 1st paragraph as allegedly failing to comply with the written description requirement.

Applicants respectfully traverse this rejection.

The Office Action asserts that the specification does not describe a representative number of sequences. Office Action, pages 6 and 7.

Applicants respectfully disagree. As an initial matter, Applicants point out that the claimed nucleotide sequences encode the amino acid sequence of SEQ ID NO: 1 (i.e., encode an amino acid sequence having I-SceI activity). Applicants submit that its disclosure of SEQ ID NO: 1 is sufficient to comply with the written description requirement. Indeed, the Manual of Patent Examining Procedure (M.P.E.P.) addresses this very situation:

For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species.

M.P.E.P. § 2163.II.A.3.a.ii; *see also In re Wallach*, USPQ2d 1939, 1942 (Fed. Cir. 2004) (citing the same M.P.E.P. section). Furthermore, Example 11 of the Written Description Training Examples makes clear that a claim directed to the genus of DNAs encoding a specific amino acid sequence complies with the written description requirement. Accordingly, the disclosure of SEQ ID NO: 1 is *prima facie* evidence that Applicants were in possession of the claimed invention.

In view of the foregoing, Applicants respectfully request withdrawal of the written description rejection.¹

Claims 24-30 stand rejected under 35 U.S.C. § 112, 1st paragraph, because the specification, while being enabling for SEQ ID NOS: 1-4, does not reasonably provide enablement for sequences which meet the limitations of claim 25 (i-c) or claim 26(a-cc).²

Applicants respectfully traverse this rejection.

The Office Action states that “Applicants only teach SEQ ID NOS: 1-4.” Office Action, page 9.

Applicants respectfully disagree. As discussed above, the specification discloses the various sequences encompassed within the claimed invention. Indeed, the specification describes the

¹ Applicants point out that claim 29 is directed to an isolated DNA sequence comprising the nucleotide sequence of SEQ ID NO: 4. The Office Action appears to acknowledge that SEQ ID NO: 4 is adequately described. Office Action, pages 6 and 7. Accordingly, Applicants respectfully request clarification as to the status of claim 29.

² Applicants respectfully request clarification as to the inclusion of claims 24, 29 and 30 in this rejection as the rejection is silent on these claims.

possible sequences that encode SEQ ID NO: 1 (i.e., encode an amino acid sequence having I-SceI activity) and specifically identifies which sequences are not allowed by the various provisos set forth in the claims. *See, e.g.*, Tables 1 and 2. Accordingly, Applicants submit that one of skill in the art would understand which sequences satisfy the provisos set forth in the claims.

As a final matter, Applicants submit that SEQ ID NO: 1 is novel and non-obvious. Indeed, as acknowledged by the Office Action, no reference teaches SEQ ID NO: 1. *See* Office Action, page 11 (“The closest prior art to SEQ ID NO: 1 identified through sequence searches was Dujon et al., 95.6% identical to SEQ ID NO: 1...”). Applicants note that the I-SceI amino acid sequence of SEQ ID NO: 1 differs, for example, from the *Saccharomyces cerevisiae* I-SceI described in WO 96/14408 and used by Puchta et al. (1996), both cited in the Information Disclosure Statement. In particular, the first four amino acids of the *Saccharomyces cerevisiae* I-SceI, Met-His-Met-Lys, have been replaced by Met-Ala-Lys-Pro-Pro-Lys-Lys-Lys-Arg-Lys-Val in SEQ ID NO: 1. Applicants respectfully submit that one of ordinary skill in the art at the time the invention was filed would have had no reason to make this replacement.

In view of the foregoing, Applicants respectfully request withdrawal of the enablement rejection.

Request for Rejoinder

Product claims 24-30 are believed to be allowable for the reasons set forth above. Process claims 5-6, 11-20 and 31-32, which were withdrawn from consideration, and newly added claims 33-36 include all the limitations of the product claims. Accordingly, as set forth in M.P.E.P. § 821.04(b), Applicants request that the restriction between claims 5-6, 11-20 and 31-32, and claims 24-30 be withdrawn and the process claims (including newly added claims 33-36) be examined for patentability in accordance with 37 C.F.R. § 1.104.

CONCLUSION

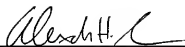
In view of the above remarks, early notification of a favorable consideration is respectfully requested.

Respectfully submitted,

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